专 利 合 作 条 约

PCT

专利性国际初步报告

（PCT 第II章）

(PCT 36 和细则 70)

申请人或代理人的档案号 IP040050	关于后续行为　　参见 PCT/IPEA/416 表	
国际申请号 PCT/CN2004/001427	国际申请日（日/月/年） 07.12 月　2004（07.12.2004）	优先权日（日/月/年） 08.12 月　2003（08.12.2003）
国际专利分类(IPC)或者国家分类和 IPC 两种分类 参见附加页		
申请人 胡军		

1. 本报告是国际初步审查单位根据条约 35 做出的国际初步审查报告，并依照条约 36 将其传送给申请人。

2. 本报告共计 4 页，包括扉页。

3. ☐ 本报告还有附件，

   a. ☐ (传送给国际局和申请人)共计 _____页，包含

   ☐修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页，和/或对本国际初步审查单位所做出的更正页(见 PCT 细则 70.16 和行政规程 607)。

   ☐国际初步审查单位认为修改超出原始公开范围的取代页，参见第 I 栏第 4 项和补充栏。

   b. ☐ （传送给国际局）共计 (指明电子载体的类型和数量) _____，包含有在与序列表有关的补充栏中指明的电子形式的序列表和/或与其相关的表格。（行政规程 802）

4. 本报告包括关于下列各项的内容：

   I ☒ 报告的基础

   II ☐ 优先权

   III ☐ 不做出关于新颖性、创造性和工业实用性的意见

   IV ☐ 缺乏发明的单一性

   V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的理由；支持这种意见的引证和解释

   VI ☐ 引用的某些文件

   VII ☐ 国际申请中的某些缺陷

   VIII ☐ 对国际申请的某些意见

提交要求书的日期 14.6 月　2005（14.06.2005）	完成本报告的日期 03.3 月　2006（03.03.2006）
中华人民共和国国家知识产权局 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号：(86-10) 62019451	受权官员 倪晓红 电话号码　(86-10)：62085753

专利性国际初步报告

国际申请号
PCT/CN2004/001427

I. 报告的基础

1. 关于语言，本报告将基于：

☒ 申请提出时使用的语言。

☐ 该申请的_____语言译文，提供该种语言的译文是

☐ 为了国际检索而提交的译文所使用的语言（细则 12.3 和 23.1（b））。

☐ 为了国际申请的公布而提交的译文所使用的语言（细则 12.4）。

☐ 为了国际初步审查而提交的译文所使用的语言（细则55.2和/或55.3）。

2. 关于国际申请中各个部分，本报告基于（申请人为答复受理局根据条约 14 所发通知而提交的替换页，在本报告中视为“原始提交”的文件，不作为本报告的附件）

☒ 原始提交的国际申请。

☐ 说明书，第_____页 原始提交的，
第_____页 _____初审单位收到的，
第_____页 _____初审单位收到的。

☐ 权利要求，第_____页，原始提交的，
第_____页，按条约 19 条修改的(附有说明)，
第_____页 _____初审单位收到的，
第_____页 _____初审单位收到的。

☐ 附图，第_____页，原始提交的。
第_____页*，_____初审单位收到的，
第_____页*，_____初审单位收到的。

☐ 序列表和/或相关表格——参见与序列表有关的补充栏。.

3. 修改导致以下内容的删除：

☐ 说明书，第 _____页

☐ 权利要求，第 _____ _____项

☐ 附图，第 _____页，图 _____

☐ 序列表 *（具体说明）* _____

☐ 与序列表相关的表格 *（具体说明）* _____

4. ☐ 由于本报告附件的(某些)修改，如下所列，被认为超出了原始公开的范围，如补充栏所示，因此本报告是按照没有修改的情况做出的(细则 70.2(c))。

☐ 说明书，第 _____页

☐ 权利要求，第 _____项

☐ 附图，第_____页，图_____

☐ 序列表（具体说明） _____

☐ 与序列表相关的表格（具体说明）_____

*如果第 4 项适用，一些或全部的文件页可能做出“被取代”标记。

专利性国际初步报告

国际申请号
PCT/CN2004/001427

V. 按条约 35 (2)关于新颖性、创造性或工业实用性的意见；支持这种理由的引证和解释

1. 意见

新颖性(N)	权利要求 1—23	是
	权利要求	否
创造性(IS)	权利要求 1—23	是
	权利要求	否
工业实用性(IA)	权利要求 1—23	是
	权利要求	否

2. 引证和解释（细则 70.7）

D1：WO03 / 044529A1

本发明涉及一种活化淋巴细胞特异性的检测方法及其培养基。

新颖性和创造性：

（1）D1 是一篇有关对于淋巴细胞活化作用的调节的物质和所用的方法，其中公开对于淋巴细胞活化作用的试剂的筛选的方法（参见说明书第 50 页第 11 行至第 53 页第 28 行），所述的方法包括：

i) 提供一种淋巴细胞，所述淋巴细胞包括在所述淋巴细胞内表达的编码 Mkk3b 蛋白从而用于产生该蛋白的核苷酸；

ii)用备选的生物活性试剂接触所述淋巴细胞；

iii)诱导所述淋巴细胞的活化；

iv)检测所述淋巴细胞在备选生物活性试剂存在时的活化作用，来确定所述备选的生物活性试剂对淋巴细胞的活化的能力。由此可见， D1 与权利要求 1 的区别是在于权利要求 1 的技术方案中所用的淋巴细胞是单核细胞用作被检样品，其培养基中添加了活化淋巴细胞增殖的细胞因子的中和抗体和 / 或诱导细胞凋亡或抑制细胞增殖和活化的细胞因子。 上述区别特征并没有在检索报告中的其它任何一篇对比文件中披露或得到技术启示，因此独立权利要求 1 及其从属权利要求 2—11 都符合 PCT33（2）规定的新颖性和 PCT33（3）规定的创造性。

（2）权利要求 12 保护一种培养基，用于检测活化淋巴细胞的特异性，其技术方案也没有在检索报告中任何一篇对比文件中揭露或得到技术启示，因此独立权利要求 12 及其从属权利要求 13—23 都符合 PCT33（2）规定的新颖性和 PCT33（3）规定的创造性。

工业实用性：

权利要求 1—23 保护的方法和培养基在生物化学工业中可使用和制造，因此符合 PCT33（4）规定的工业实用性。

补充栏

当前面的任何一栏地方不够时使用

续栏：G01N33/53（2006.01）i

C12N5/00 (2006.01）i

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IP040050	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN2004/001427	International filing date *(day/month/year)* 07.Dec. 2004(07.12.2004)	Priority date *(day/month/year)* 08.Dec. 2003(08.12.2003)
International Patent Classification (IPC) or national classification and IPC See the extra sheet		
Applicant HU, Jun		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.Jun. 2005(14.06.2005)	03.Mar. 2006(03.03.2006)
Name and mailing address of the IPEA/CN The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer NI, Xiaohong Telephone No. (86-10)62085753

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001427

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rules 12.3(a) and 23.1(b))

☐ publication of the international application (Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished

pages * _____ as amended (together with any statement)under Article 19

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001427

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims	1-23	YES
	Claims		NO
Inventive step (IS)	Claims	1-23	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

D1:WO03/044529A1

This invention relates to a method of assaying specification of activated lymphocyte and the culture medium thereof.

NOVELTY AND INVENTIVE STEP:

D1 is the closest art to this invention which provides compositions and a method of modulating lymphocyte activation and discloses a method of screening for a bioactive agent capable of modulating lymphocyte activation(see page 50, line 11 to page 53, line 28 in D1), said method comprising:

i) providing a lymphocyte, said lymphocyte comprising a recombinant nucleic acid encoding an Mkk3b protein which is expressed in said lymphocyte to produce recombinant Mkk3b protein;ii) contacting said lymphocyte with a candidate bioactive agent;iii)inducing activation of said lymphocyte; and iv) determing the activation of said lymphoctye in the presence of said candidate bioactive agent; and wherein a change in the activation of said lymphocyte in the presence of said candidate bioactive agent indicates that said candidate bioactive agent is capable of modulating lymphocyte activation. As said above, the difference between claim 1 and D1 is that in claim 1 monocyte is used as specimen which is the suspect lymphocte and culture memdium is added a kind of neutralizing antibody, a cell factor added into a culture medium of which proliferates lymphocyte activation and/or another cell factors which can induce apoptosis or inhibit proliferation and activation. The difference is not disclosed or suggested by any other document in ISR, so the independent claim 1 and dependent claims 2-11 have novelty for PCT Article 33(2) and inventiveness for PCT Article 33(3).

Claim 12 is the culture medium which is used to assay specification of activated lymphocyte which is not disclosed or suggested by any document in the ISR, so independent claim 12 and dependent claim 13-23 all have novelty for PCT Article 33(2) and inventive step for PCT Article 33(3).

INDUSTIAL APPLICABILITY:

Claims 1-23 meet the criteria set out in PCT Aritcle 33(4) for industrial applicability since the method and the culture medium thereof can be made or used in biochemistry industry.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
G01N33/53 (2006.01) i
C12N5/00 (2006.01) i